

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR
ADEQUATE DIRECTIONS OR WARNING STATEMENTS**

DRUGS AND DEVICES FOR HUMAN USE*

7015. Frye's remedies. (F.D.C. No. 45924. S. Nos. 79-326 R, 79-329/31 R, 79-333 R, 79-336/9 R.)

QUANTITY: 42 cases, 12 1-pt. btls. each, of *Frye's Laxative Syrup*; 2 cases, 12 1-pt. btls. each, of *Frye's Gentian Iron Tonic*; 17 cases, 12 1-pt. btls. each, of *Frye's Rheumatine Compound No. 50*; 54 100-tablet btls. of *Meditron*; and 12 cases, 12 8-oz. btls. each, of *Frye's Compound Wine of Comfrey*, at Kingsport, Tenn., in possession of Charles T. Frye.

SHIPPED: Between 12-2-59 and 3-30-61, from Philadelphia, Pa.

LABEL IN PART: (Btl.) "Frye's Laxative Syrup * * * Prepared for C. T. Frye, 1926 Knoxville Highway P.O. Box 826-Kingsport, Tenn."; "Frye's Gentian Iron Tonic * * * Iron-Gentian Improved with Vitamins B₁ and B₂ Plus Lipotropic Agents and B Complex Factors * * * Distributor C. T. Frye"; "Frye's Rheumatine Compound No. 50 * * * Prepared for C. T. Frye, 1926 Knoxville Highway, P.O. Box 826-Kingsport, Tenn."; "Tablets Hance Meditron"; "Frye's Compound Wine of Comfrey Restorative Wine Bitters * * * Distributor C. T. Frye, P.O. Box 826-Kingsport, Tenn."

LIBELED: 6-9-61, E. Dist. Tenn.

CHARGE: 502(f) (1)—while held for sale, the labeling of the articles, namely, the bottle labels, failed to bear adequate directions for use for the purposes for which they were intended, namely, (*Frye's Laxative Syrup*) for the treatment of conditions of the liver; (*Frye's Gentian Iron Tonic*) for the treatment of weakened, rundown conditions, gaining strength, and building up the body; (*Frye's Rheumatine Compound No. 50*) for the treatment of rheumatism and arthritis, and for removing poisons from the blood; (*Meditron*) for the treatment of arthritis and rheumatism; and (*Frye's Compound Wine of Comfrey*) for the treatment of internal bleeding in women; for healing and stopping pains of menstruation; and for irregular menstruation. The articles were offered for such purposes in oral representations made by C. T. Frye.

DISPOSITION: On 7-20-61, Charles T. Frye, claimant, filed an answer denying that the articles were misbranded. Thereafter, on 3-7-62, the claimant having consented to the condemnation of the articles and the entry of an injunction, a decree was entered condemning the articles and permanently enjoining the claimant, his agents, employees, representatives, and all other persons in active concert or participation with him, from holding for sale or causing to be held for sale after shipment in interstate commerce, any of the articles or any similar articles which fail to bear in their labeling: (1) All of the conditions, purposes, and uses for which such articles are intended to be used and for which they are represented, by any means, to the public; and (2) sufficient information to enable the layman to use such articles for such purposes safely, intelligently, and efficaciously, and from doing any act with respect to such articles while held for sale after shipment in interstate commerce, which represents and suggests by means of oral statements that the articles are adequate and effective for diseases and conditions of man. In accordance with the consent decree, the articles were released under bond to be brought into compliance with the law.

*See also Nos. 7003, 7004, 7007-7011.